

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

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| DANIEL HUBERT, individually and on behalf of | : | Civil Action No. 2:15-cv-01391-MRH |
| all others similarly situated, | : | |
| | : | |
| Plaintiff, | : | |
| | : | Oral Argument Requested |
| v. | : | |
| | : | |
| GENERAL NUTRITION CORPORATION, | : | This Document Relates to: |
| | : | All Actions |
| | : | |
| Defendant. | : | |
| | : | |
| (In re: GNC Picamilon/BMPEA Litigation) | : | |

**DEFENDANT GENERAL NUTRITION CORPORATION'S BRIEF IN SUPPORT
OF MOTION TO DISMISS**

Defendant General Nutrition Corporation (“GNC”), by and through its attorneys Amy B. Alderfer, Esquire, Paul K. Leary, Jr., Esquire, and Brett N. Taylor, Esquire, and the law firm Cozen O’Connor, file the following Brief in Support of GNC’s Motion to Dismiss Plaintiffs’ Second Amended Consolidated Class Action Complaint pursuant to Federal Rule of Civil Procedure 12(b)(1) and (6), for lack of subject matter jurisdiction and for failure to state a claim upon which relief can be granted.

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MEMORANDUM

I. INTRODUCTION

This action stems from claims by Plaintiffs regarding Products they allegedly bought from GNC that contained BMPEA, picamilon and/or acacia rigidula. GNC acted as a retailer for these Products, and the Products were neither manufactured nor distributed by GNC. Plaintiffs' claim that the Products are unlawful because they violate various requirements set forth by the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* The allegations of unlawful claims all stem from alleged statements and/or omissions on the Product bottles themselves, not any display or information pamphlet given to Plaintiffs by GNC.

As with their prior complaints, Plaintiffs continue to fail to allege that they were injured by the Products and/or that they took the Products and the Products did not work as intended. This is now Plaintiffs' **third attempt** to plead a viable case against GNC. As with Plaintiffs' prior attempts, they have failed to properly plead a cause of action against GNC for the following reasons:

First, Plaintiffs lack standing because they have failed to plead an injury stemming from the Products at issue. Although the Court's Opinion and Order granting GNC's Motion to Dismiss Plaintiffs' First Amended Complaint (the "FAC") detailed precisely how Plaintiffs' First Amended Complaint failed to properly allege standing, Plaintiffs' Second Amended Consolidated Complaint ("SAC") fails to remedy those deficiencies. *Second*, Plaintiffs' claim for violations of the Magnuson-Moss Warranty Act fail because that act does not apply to written warranties governed by federal laws such as the FDCA.

Third, each of the Plaintiffs' claims is preempted by federal law. Congress vested authority to enforce the FDCA exclusively in the federal Food & Drug Administration ("FDA"). A review of the Complaint makes clear that Plaintiffs are attempting to enforce this same statute,

but their claims would not exist were it not for the FDCA so they are preempted. Furthermore, Plaintiffs claim that the dietary supplements were being sold unlawfully at the time they purchased the Products, however, such claims would be directly in contradiction to the FDCA as the FDA had not made any statements that the ingredients were unlawful, and to the contrary, had provided FDA Certificate of Free Sale for picamilon stating otherwise.

Fourth, there has been no enforcement action by the FDA regarding picamilon, BMPEA, or acacia rigidula, let alone a final agency action. Instead, as part of a back-door litigation strategy, the OAG procured a declaration from Dr. Cara Welch—the same FDA official who only four short months earlier signed an FDA Certificate of Free Sale for picamilon-containing products. GNC had no opportunity to respond to this declaration through the typical statutory administrative procedures—a violation of GNC’s due process rights. The administrative procedures must play out and the FDA must take final agency action before the Plaintiffs can sustain claims against GNC.¹

Fifth, GNC is the retailer, not the manufacturer or distributor, of the Products that are subject to the action, and the FDA regulations dealing with premarket notifications that Plaintiffs allege GNC violated apply to manufacturers and distributors, not retailers. As a retailer, GNC relied upon guarantees from its vendors who distributed the Products to GNC. Consistent with the FDCA, the vendors warranted that the products sold to GNC were lawful. That reliance is justified under the “FDA Guarantee,” discussed below. And once questions began to surface about the legal status of BMPEA, picamilon and acacia rigidula as dietary ingredients, GNC voluntarily took immediate steps to remove these ingredients from its shelves. GNC started removing BMPEA a full 12 days before any FDA warning letters were sent to others. Picamilon

¹ We note that industry commentators are also concerned that the FDA has delegated its authority to the states by doing so has violated due process standards by issuing a declaration with no administrative mechanism for GNC to appeal. See, e.g., <http://www.usatoday.com/story/news/2015/10/22/oregon-lawsuit-gnc-supplements/74344318/>.

was removed by GNC more than 60 days before any FDA warning letter. Regarding acacia rigidula, the FDA did not take any action whatsoever regarding it until March 2016, almost a year after GNC had removed products containing acacia rigidula from its shelves.

Plaintiffs have had numerous chances to amend their deficiencies and have not because they cannot. Based on the above, the Court should dismiss Plaintiffs' SAC in its entirety, with prejudice.

II. LEGAL STANDARDS

A. Lack of Subject Matter Jurisdiction Under FRCP 12(b)(1)

Federal Rule of Civil Procedure 12(b)(1) governs a motion to dismiss for lack of standing, since "standing is a jurisdictional matter." *Ballentine v. United States*, 486 F.3d 806, 810 (3d Cir. 2007). Standing is a threshold question of subject matter jurisdiction that must be satisfied before a plaintiff may bring a cause of action in federal court. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992); *Pub. Interest Research Group of N.J. v. Magnesium Elektron, Inc.*, 123 F.3d 111, 117 (3d. Cir. 1997). A court may not create jurisdiction by curing deficient standing allegations. *Whitemore v. Arkansas*, 495 U.S. 149, 155–56 (1990). The plaintiff bears the burden of establishing that jurisdiction exists. *Petruska v. Gannon Univ.*, 462 F.3d 294, 302, n. 3 (3d Cir.2006).

B. Failure to State a Claim Under FRCP 12(b)(6)

To survive a motion to dismiss for failure to state a claim, a complaint must contain factual allegations sufficient to "raise a right to relief above the speculative level." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). A plaintiff must plead affirmative factual content that "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 1949 (2009).

A complaint should be dismissed where “it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations.” *Famology.com, Inc. v. Perot Systems Corp.*, 158 F. Supp. 2d 589, 590 (E.D. Pa. 2001) (citing *H.J. Inc. v. Northwestern Bell Tel. Co.*, 492 U.S. 229, 249-50 (1989)). Although the court must accept as true the facts alleged in the complaint, the court “need not credit a plaintiff’s ‘bald assertions’ or ‘legal conclusions’ when deciding a motion to dismiss.” *Id.* at 591 (citing *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997)).

C. Judicial Notice and Documents Relied Upon by Plaintiffs

Although the purpose of a motion to dismiss is to test the legal sufficiency of a plaintiff’s claims, reading allegations in the light most favorable to the plaintiff, the court is not required to reason in a vacuum. *See Wright & Miller, Federal Prac. and Procedure* § 1357, at 376. At any stage of the proceeding, the court may take judicial notice of facts “not subject to reasonable dispute” because such facts are “generally known” or “capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.” Fed. R. Evid. 201(b). Documents under the seal of the Secretary of the Department of Health and Human Services made in connection with the function of the Department “shall be judicially noticed” under the plain language of 42 U.S.C. § 3505. (See Declaration of Steven Cherry (“Cherry Dec.”) and Request for Judicial Notice, Ex. D)

On a motion to dismiss, “a court may consider an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff’s claims are based on the document.... Moreover, a document that is integral to or explicitly relied upon in the complaint may be considered in a motion to dismiss....” *Karl v. Donaldson, Lufkin & Jenrette Sec. Corp.*, 78 F. Supp. 2d 393, 395 n.4 (E.D. Pa. 1999) (Emphasis Added); *see also Pension Benefit Guar. Corp. v. White Consol. Indus.*, 998 F.2d 1192, 1196 (3d Cir. 1993) (were the law

otherwise, “a plaintiff with a legally deficient claim could survive a motion to dismiss simply by failing to attach a dispositive document on which it relied”).

III. STATEMENT OF FACTS/PROCEDURAL HISTORY

A. Pending Oregon Litigation

On October 22, 2015, the Attorney General for the State of Oregon (“OAG”) sued GNC in Oregon state court.² The OAG’s Complaint depends entirely on the predicate allegation that GNC violated the FDCA. (Declaration of Stephen Cherry, Ex H.) The Complaint is pleaded under a state statute, Oregon’s Unlawful Trade Practices Act (“UTPA”). The OAG did not allege, however, that GNC violated some independent provision of state law governing ingredients in dietary supplements. Rather, the OAG alleged that GNC violated the UTPA by selling dietary supplements containing Picamilon or BMPEA, which, according to the OAG, were not “lawful dietary ingredients” under the FDCA during the time period when GNC sold such dietary supplements. The central allegation of the Complaint is that by violating the federal FDCA, GNC also violated the UTPA. (*Id.* Pg. 1, lines 15-19) In reality, the FDA had never pronounced that either ingredient was unlawful or unsafe prior to 2015 – to the contrary, the FDA’s public record was indicative of their legality and safety.

B. The Dr. Cara Welch Declaration and Certificate of Free Sale

A declaration signed by Dr. Cara Welch, PhD is the evidentiary centerpiece for the picamilon portion of the OAG action and the present case. It is the *only* support relied upon for the legal conclusion that picamilon is not a lawful dietary ingredient. This declaration was solicited in the context of litigation by the OAG as leverage to force a quick payout from GNC.

² References to “OAG Action” herein refer to the Oregon litigation, United States District Court for the District of Oregon, Case number 3:15-cv-02006-PK. References to “OAG” refer to Mr. David Hart, Assistant Attorney in Charge for the Health Fraud Unit/Consumer Protection Section at the Oregon Department of Justice. The Attorney General of Oregon is Ellen Rosenblum.

(Cherry Dec. ¶ 8.)³ Dr. Welch’s Declaration was not the result of spontaneous agency action, but rather was drafted at the specific request of the OAG for use in litigation. Fittingly, the declaration is attached as an exhibit to the OAG’s Complaint but the declaration was never provided by the FDA to GNC. (*Id.* ¶ 14.)

Dr. Welch’s Declaration is troubling not only because of the context surrounding its creation, but also because it is notably inconsistent with a Certificate of Free Sale signed by Dr. Welch just months earlier. On April 15, 2015, Dr. Welch affixed her signature to a Certificate of Free Sale for two picamilon-containing products, namely, RIPTEK V2 and TESTEK. (*Id.* ¶ 7, Ex D.)⁴ The Certificate bears the office seal of the Department of Health and Human Services.

According to FDA’s website, a Certificate of Free Sale indicates that a particular product is marketed in the United States or eligible for export, “and that the particular manufacturer has no unresolved enforcement actions pending before or taken by FDA”. These certificates may be issued by FDA or by a State governmental authority.⁵ The Certificates in essence announce to the world that the subject products are freely (and lawfully) available for sale in the U.S. And importantly they are relied upon by, among others, GNC vendors and foreign regulatory bodies that are responsible for decisions to approve products for sale in their countries. Thus, as of April 15, 2015, the FDA’s public position is that picamilon was (at least impliedly) a lawful dietary ingredient. The Certificate, attached as Exhibit D to the Declaration of Stephen Cherry filed herewith, is a self-authenticating public document and this court should take judicial notice of its existence and content. 12 U.S.C. § 3505; Fed. R. Evid. 201(b); 902(1).

³ An email the OAG sent to GNC’s local counsel in Oregon, Mr. Hart stated that GNC “should be aware of the assistance that FDA is providing in this matter.” (Cherry Dec. ¶ 9, Ex. F.) He went on to state that the declaration “will be used in any litigation” and then advised that the OAG’s Complaint would seek civil penalties going back to 2007. (*Id.*) In order for GNC to stave off the Oregon litigation, it would have had to pay well in excess of \$1,000,000. (*Id.* ¶ 12.)

⁴ These two products are manufactured by QNT International, Inc. and are two of the products included in Plaintiffs’ Complaint.

⁵ <http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/ucm2006911.htm>. (Alderfer Dec., Ex I.)

On September 29, 2015, within minutes of learning of Dr. Welch's contrary declaration and out of an abundance of caution, GNC immediately removed ALL products containing picamilon from its shelves. (Cherry Dec. ¶ 10.)

Dr. Welch signed her declaration on September 28, 2015. More than 60 days thereafter, the FDA made its first public statement regarding picamilon by issuing warning letters on November 30, 2015, to five **manufacturers** of products containing picamilon.⁶ This conspicuous inaction leads to the inescapable conclusion that Dr. Welch's declaration had but one purpose when it was written: to assist the OAG in litigation. Despite Dr. Welch's apparent complete reversal of position on picamilon, it took the FDA more than two months to issue a single warning letter. (Cherry Dec. ¶ 11.) As noted above, GNC as a retailer has never received any notices from FDA about picamilon (or BMPEA) and by November 30 all picamilon-containing products had been off GNC's shelves for sixty days or more. (Cherry Dec. ¶¶ 10, 11.)

C. The Instant Action

On February 29, 2016, Plaintiffs filed the Consolidated Class Action Complaint in this matter. Plaintiffs are now on their third try pleading this case. On April 27, 2016, Plaintiffs filed a First Amended Complaint ("FAC") that was nearly identical to the Original Consolidated Complaint except for adding allegations regarding acacia rigidula, adding a plaintiff (Nate Picone) and deleting a cause of action for Breach of Implied Warranty under California's Song Beverly Consumer Warranty Act. In what has now become a pattern of conduct, Plaintiffs' SAC failed to remedy any of the defects pointed out in GNC's previous motion to dismiss and the Court's order granting GNC's motion to dismiss.

A careful examination of the SAC reveals that it is just more of the same, and that Plaintiffs were unable to correct the deficiencies noted in the court's September 8, 2017 Opinion.

⁶ <http://www.fda.gov/food/dietarysupplements/productsingredients/ucm472881.htm>. (Alderfer Dec., Ex. J.)

On page 5 of the Court’s Opinion, the Court sums up Plaintiffs’ FAC as follows: “Plaintiffs claim that through this labeling, GNC misrepresented that those substances were safe and could be legally sold in the United States. (citation omitted). As a result, Plaintiffs assert that they purchased supplements they otherwise would not have purchased, paid more for supplements than they otherwise would have paid and have been subjected to unreasonable safety risks.” (citations omitted.) (Opinion at p. 5.) The SAC pleads the same core facts: Plaintiffs were “hoodwinked” into purchasing “mislabeled products that they otherwise would not have purchased (SAC para. 6); They paid more than they would otherwise have paid (SAC ¶ 6); and the products had no history of safe usage (SAC ¶ 4).

As is set forth below, once again, Plaintiffs have failed to cure their defective complaint, and it is now apparent that they cannot. As such, any further request by Plaintiffs for leave should be denied. *See Vasquez v. L.A. Cnty.*, 487 F.3d 1246, 1258 (9th Cir. 2007) (“Granting Vasquez leave to amend would have been futile, and we hold that the district court did not err in preventing such futility.”).

i. **Picamilon**

Once again, Plaintiffs allege that picamilon does not qualify as a dietary ingredient under the FDCA and that it is not a lawful dietary ingredient. (SAC ¶ 47.) In support of this legal conclusion, Plaintiffs have relied on the allegations in the OAG Action for support, citing to four pieces of “evidence”: (1) the September 28, 2015 Welch Declaration discussed in detail above; (2) Russian literature; (3) the Investigative Demand to GNC made by the OAG; and (4) and a study regarding the accuracy of supplement labeling set forth in paragraph 52 of the SAC. This “evidence” is apropos of nothing for the simple reason that the FDA has taken no enforcement action regarding picamilon and there has been no final agency action as to picamilon’s lawfulness.

ii. BMPEA

Plaintiffs again allege that GNC sold third-party products that contained BMPEA, including products containing an ingredient labeled as *acacia rigidula* when in fact the product was actually spiked with BMPEA. Plaintiffs attempt to shift their focus somewhat arguing that GNC misrepresented to Plaintiffs and consumers that BMPEA was a lawful dietary ingredient when in fact it was not and, therefore, the products could not be “dietary supplements.” However, just like in prior iterations, the SAC is conspicuously absent of any reference whatsoever to an enforcement action or final action by the FDA relating to BMPEA or *acacia rigidula*. The reason, of course, is there were none. While Plaintiffs may be shifting the focus of its pleadings in an attempt to avoid dismissal, they cannot avoid the fact that GNC *never* received a notice of any kind from FDA regarding BMPEA but had already begun removing BMPEA products from its shelves a full 12 days before the April 22, 2015, FDA warning letters were issued. (*Id.* ¶¶ 3-6.) Plaintiffs admit that GNC voluntarily stopped selling products identified as containing BMPEA immediately after the April 22, 2015 warning letters were issued.

iii. Acacia Rigidula

Plaintiffs’ allegations regarding *acacia rigidula* follow the same precarious and now well-traveled path as their allegations regarding picamilon and BMPEA. Like with picamilon and BMPEA, there has been no final agency action concerning *acacia rigidula* and, in fact, GNC had removed products containing *acacia rigidula* from its shelves long before the FDA issued its warning letters.

On or about April 25, 2015, GNC began pulling all products containing *Acacia rigidula* from its shelves. (Cherry Dec. ¶ 12.) This was almost a year before the FDA issued its March 7, 2016 warning letters to six other entities (not GNC) regarding *Acacia rigidula*. (SAC ¶ 61;

Cherry Dec., Ex. H.)

IV. PLAINTIFFS' CLAIMS SHOULD BE DISMISSED

A. Plaintiffs Lack Standing to Pursue Their Claims.

Standing is a threshold jurisdictional requirement derived from Article III's case-or-controversy requirement. U.S. Const. art. III, § 2, cl. 1. To satisfy "the irreducible constitutional minimum of standing," the plaintiff bears the burden of establishing three elements:

First, the plaintiff must have suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical. Second, there must be a causal connection between the injury and the conduct complained of—the injury has to be fairly ... trace[able] to the challenged action of the defendant, and not ... the result [of] the independent action of some third party not before the court. Third, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Lujan v. Defenders of Wildlife, 504 U.S. 555, 560–61 (1992) (internal citations omitted).

Although all three elements must be met, "the injury-in-fact element is often determinative."

Toll Bros., Inc. v. Twp. of Readington, 555 F.3d 131, 138 (3d Cir. 2009).

In its detailed Opinion dismissing Plaintiff's FAC, the Court noted that Plaintiffs claimed that they purchased supplements they otherwise would not have purchased, paid more for supplements than they otherwise would have paid, and have been subject to unreasonable safety risk. (Opinion p. 5.) The Court found that these allegations as pleaded were not sufficient to establish standing. As discussed below, despite being given yet another chance to plead their claims, Plaintiff's SAC fares no better than the two prior iterations and simply restates the same core allegations already rejected by the Court. Once again, Plaintiffs have failed to plead a viable economic injury-in-fact sufficient to establish standing. As such, Defendants request that the Court dismiss Plaintiffs' SAC with prejudice.

1. Plaintiffs' Premium Price Allegations Do Not Establish that They Suffered an Economic Injury.

Just as they did in the FAC, Plaintiffs continue to present nothing more than threadbare allegations claiming that GNC's alleged misrepresentations and alleged omissions "hoodwinked" Plaintiffs into paying more for the supplements than they otherwise would have paid. (SAC ¶ 6.) Plaintiffs once again fail to plead any facts alleging how they may have paid a premium for the supplements at issue. For example, Plaintiffs plead no facts alleging that GNC advertised the supplements as superior to other products. Rather, Plaintiffs make vague references to GNC's "practices" without ever detailing these "practices" and how these "practices" resulted in consumers paying a premium for the supplements. (SAC ¶ 87.) Similarly, Plaintiffs fail to demonstrate that there were other comparable, cheaper products on the market. As the Court explained in its detailed Opinion, this is fatal to Plaintiffs' standing. *See Young v. Johnson & Johnson*, 2012 WL 1372286 (2012) *4 (noting that plaintiff failed to plead any facts as to how he allegedly paid a premium for Benecol).

2. *Plaintiffs' Argument That They Would Not Have Bought the Product Fails to Establish Injury in Fact.*

As in the FAC, Plaintiffs allege that they paid money for the supplements that, absent GNC's alleged misrepresentations and omissions, they otherwise would not have paid. (SAC ¶ 6.) While Plaintiffs now allege that they consumed the supplements, which they describe as "primarily weight-loss and sports-nutrition supplements available as powders and liquids", nowhere do they claim that they suffered any adverse health consequences as a result. (SAC ¶ 28.) Moreover, Plaintiffs do not allege that the products failed to actually work for their intended purpose of weight loss and/or sports nutrition. *James v. Johnson & Johnson Consumer Companies*, 2011 WL 198026 (2011) and *Medley v. Johnson & Johnson Consumer Companies, Inc.*, 2011 WL 159674 (2011) are instructive.

In both *James* and *Medley*, the product at issue was Johnson & Johnson baby's shampoo. Plaintiffs alleged that the shampoo they had purchased violated the FDA's ban on methyl chloride in cosmetic products because its baby shampoo contained that substance. Both courts found that even though plaintiffs would not have bought the product had they known it contained methyl chloride, economic damages did not automatically follow as a consequence. The reason being that there was no economic injury in that the plaintiffs received the benefit of the bargain – a shampoo that worked as intended. Noting that plaintiffs had apparently used the product in bathing their children without adverse health reactions, both courts held that plaintiffs did not have standing based on economic injury in fact. The *James* court stated that "Plaintiffs received the benefit of their bargain so long as there were no adverse health consequences, and the product worked as intended, meaning that the hair of Plaintiffs' children was cleansed, and their eyes and skin were not irritated." 2011 WL 198026 *2. The court in *Medley* found no standing based on economic injury-in-fact holding that: "[P]laintiffs received the benefit of the bargain so long as there were no adverse health consequences, and the product worked as intended." 2011 WL 159674 (2011).

Here, just as in *James* and *Medley* Plaintiffs allege that they would not have bought the supplements had they known certain alleged facts. However this claim fares no better here than it did in *James* and *Medley*. As was the case in *James* and *Medley*, the instant SAC lacks any allegation of Plaintiffs suffering any adverse health consequences. Similarly, there is no allegation that the supplements purchased by Plaintiffs failed to work as intended. In fact, Plaintiffs own pleading suggests that the supplements worked as intended as Plaintiffs allege that they purchased and consumed the supplements multiple times over periods of month and years. Consider the following allegations:

(1) Plaintiff Daniel Hubert purchased and consumed the same supplement on *five* occasions from January to May 2015 (SAC ¶ 11.); (2) Plaintiff Kyle Eager purchased and consumed the same supplement in different flavors on two occasions in 2015 (SAC ¶ 12.); (3) Plaintiff Robert Brooks purchased and consumed supplements on multiple occasions between June 2013 and June 2014 (SAC ¶ 13.); (4) Plaintiff Malecha purchased and consumed numerous supplements over a period of three years (SAC ¶ 19.); and (5) Plaintiffs Cesario, Johnston, Landuit-Vartanian, Malecha, Lambert, and Toth all purchased and consumed various products on “multiple” occasions. (SAC ¶¶ 15, 17, 18, 20, 21.)

Not only do Plaintiffs not allege that the supplements failed to work as intended; but rather they admit that they repeatedly bought and consumed the supplements over a sustained period of time. This is virtually identical to the plaintiff in *Estrada v. Johnson & Johnson*, No. CV 16-7492 (FLW), 2017 WL 2999026, at *11 (D.N.J. July 14, 2017) who purchased and used baby powder for a substantial period of time only to later claim that she would not have done so had she known that using it in the genital area lead to an increased risk of cancer. The court in *Estrada* found that plaintiff’s failure to allege that the baby powder was ineffective for its intended use coupled with her repeated purchases and consumption amounted to a failure to allege facts sufficient to establish an economic injury-in fact. The same is true here. Plaintiffs’ failure to allege that the supplements failed to work, along with their pleading that they bought the supplements repeatedly over years makes a finding of economic injury-in-fact impossible.

3. *Plaintiffs Were Not Deprived of the benefit of their bargain based on alleged misrepresentations or omissions by GNC.*

In its Opinion dismissing Plaintiffs’ FAC, the Court noted that Plaintiffs appeared to base their benefit of the bargain theory in the FAC upon GNC’s alleged omissions and misrepresentations claiming that GNC sold products with false and misleading labeling, and it

otherwise failed to disclose material facts about the dangers of ingesting picamilon, BMPEA and acacia rigidula. (FAC ¶ 5.) The Court went on to explain that Plaintiffs did not allege what material facts GNC failed to disclose about the dangers of ingesting those substances or whether GNC had a duty to do so. As such, the Court could not conclude that Plaintiffs did not receive the benefit of their bargain based on alleged omissions by GNC.

In *Estrada* the court considered plaintiff's allegations that she suffered an economic injury-in-fact because she did not receive the benefit of the bargain when she purchased Johnson & Johnson baby powder. Specifically, plaintiff claimed that she bought the product believing it was safe and, if she had known that using it in the genital area led to an increased risk of developing ovarian cancer, she would not have purchased the product. The court held that plaintiff could not establish economic injury based on her allegation that she did not receive the benefit of her bargain based upon defendants' alleged omissions. The court noted that absent an allegation of adverse health consequences from using the product or that the product failed to perform satisfactorily for its intended use, plaintiff could not claim that she was denied the benefit of her bargain. *See also Koronthaly v. L'Oreal USA, Inc.*, 374 Fed. Appx. 257, 259 (2010) (purchasing lipstick containing lead did not form the basis for a breach of contract claim and therefore, plaintiff could not claim she had been denied the benefit of any bargain.).

Here, as set forth above Plaintiffs have failed to allege that the supplements did not work as intended. Moreover, Plaintiffs' SAC fails to allege that Plaintiffs suffered any adverse health consequences by using the supplements. Thus, like the plaintiffs in *Estrada* and *Koronthaly*, Plaintiffs' allegations regarding GNC's alleged omissions simply cannot form the basis of any benefit of the bargain theory of loss.

4. *Plaintiffs' Allegations of Inducement Fail to Establish Injury-in-Fact.*

Plaintiffs allege that GNC “advertised and marketed its supplements with the intent to induce Plaintiffs and Class members to purchase the Products.” At the core of this is the allegation that GNC used misrepresentations and/or omissions to effect this inducement. However, Plaintiffs fail to allege what specific affirmative misrepresentations were made by GNC that induced each Plaintiff to purchase particular supplements. Here, just as in *Estrada*, Plaintiffs provide no specificity whatsoever regarding what (if any) statements they read that they relied on and which induced them in purchasing the supplements.

Moreover, there is no allegation in the SAC that any of the ingredients in the supplements were hidden or concealed from Plaintiffs. In fact, Plaintiffs *admit* that picamillion, BMPEA, and acacia rigidula were openly listed on the supplement labels, and that they reviewed the labels. (SAC ¶¶ 23, 50, 57, 76.) Thus, the presence of these substances cannot form the basis for any omission. Nor can reading the label and believing that the ingredients and the supplements are safe substantiate an injury-in-fact. *Estrada* at *12 (noting that the statements cited by plaintiff lacked specificity to substantiate an injury). Plaintiffs have, once again, failed to establish that they have standing to bring the present action.

In sum, Plaintiffs’ premium price allegations, claims that they would not have bought the products, claims that they were denied the benefit of the bargain, and claims of inducement, fail to establish an injury-in-fact which confers standing. As such, the SAC should be dismissed in its entirety with prejudice.

B. Plaintiff’s Magnuson-Moss Warranty Act Claim Fails Because the Products at Issue Are Subject to The Regulatory Scheme of the FDCA.

The Magnuson-Moss Warranty Act is “inapplicable to any written warranty the making or content of which is otherwise governed by Federal law.” 15 U.S.C. § 2311(d).

Dietary supplements are subject to extensive regulation by the FDA pursuant to the FDCA, and the FDA has exclusive regulatory authority under the FDCA. See 21 U.S.C. § 371

(giving the FDA regulatory authority over the enforcement of the FDCA). It is black letter law that no private individual may bring an action to enforce the FDCA. 21 U.S.C. § 337(a). The FDCA's text and the FDCA's legislative history make clear that Congress intended the government, not private parties, to have exclusive responsibility for enforcing the provisions of the FDCA.

Here, the only alleged "warranties" that Plaintiffs claim is that "GNC warranted that the Products were fit for their ordinary purpose, to supplement the diet with dietary ingredients, and would pass without objection in the trade." (SAC ¶ 102.) Such allegations rely solely on the referenced labeling on the Products set forth in the SAC. The labeling of the dietary supplements at issue are subject to the regulatory scheme of the FDCA and, therefore, Plaintiff cannot use the Magnuson-Moss Warranty Act to attack label statements on the Products. *See e.g. Bates v. Gen. Nutrition Ctrs., Inc.*, 897 F. Supp. 2d 1000, 1002 (C.D.Cal. 2012) (Magnuson-Moss Warranty Act does not apply because the FDCA governs labeling of dietary supplements); *see also Stewart v. Smart Balance, Inc.*, 2012 U.S. Dist. LEXIS 138454, *40-41 (D.N.J. June 25, 2012); *Hairston v. S. Beach Beverage Co.*, No. CV 12-1429-JFW DTBX, 2012 WL 1893818, at *5 (C.D. Cal. May 18, 2012); *Kanter v. Warner-Lambert Company*, 99 Cal. App. 4th 780, 797, (2002) (holding that the Magnuson-Moss Warranty Act did not apply because, among other reasons, "the FDCA and its implementing regulations govern the labeling at issue"); *Jasper v. Musclepharm Corp.*, 2015 U.S. Dist. LEXIS 64588 (D. Colo. Apr. 9, 2015)(same). Therefore, Plaintiffs' first count should be dismissed with prejudice.

C. Plaintiffs' Claims Are Preempted.

i. Plaintiffs Have No Viable State Law Claims Because They Are All Predicated on Violation of the FDCA.

Plaintiffs have also failed to state a claim under Federal Rule of Civil Procedure 12(b)(6) because their claims are preempted, and preemption is manifest in the complaint itself. The Complaint should be dismissed on this ground, as well.

As a general matter, the FDCA prohibits the "introduction or delivery for introduction into interstate commerce any food . . . that is adulterated." 21 U.S.C. § 331(a). The FDCA's primary focus is ensuring that drugs are "safe, effective and not misbranded," which the FDA ensures by enforcing the regulations. *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230 (2d Cir. 1990). The statute requires the United States (e.g., the FDA) to enforce its provisions through injunctions, fines or imprisonment, or seizure of the adulterated food. 21 U.S.C. §§ 332-334. As stated above, a private individual cannot bring an action to enforce the FDCA. 21 U.S.C. § 337(a).

Not only are direct claims under the FDCA outlawed, courts have also resoundingly rejected plaintiffs' push to invent an implied right of action for private parties to directly enforce the FDCA. Multiple lower courts have uniformly held that "Congress did not intend, either expressly or by implication, to create a private cause of action under the FDCA." *Bailey v. Johnson*, 48 F.3d 965, 968 (6th Cir. 1995) (emphasis added).

Over the years, plaintiffs have tried a variety of tactics to evade the federal government's exclusive enforcement authority under Section 337 of the FDCA. Some plaintiffs, like those here, tried to bury their FDCA claims in state-law causes of action. Courts have distinguished viable claims and preempted claims in the following manner:

The plaintiff must be suing for conduct that violates the FDCA . . . but the plaintiff must not be suing because the conduct violates the FDCA (such claim would be impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 641 (2001))). For a state law claim to survive, then, the claim must be premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under the state law even in the absence of the FDCA.

Riley v. Cordis Corp., 625 F. Supp. 2d 769, 777 (D. Minn. 2009) (emphasis added); see *In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales Prac. Litigation*, 701 F. Supp. 2d 356,

369 (E.D.N.Y. 2010). “In other words, a state law claim only endures if it manages to incorporate, but not depend entirely upon, an FDCA violation and is premised on conduct that would give rise to liability under traditional common law principles.” *In re Bayer Corp.*, 701 F. Supp. 2d at 369.

Plaintiffs’ SAC again contains references to the alleged unlawfulness of picamilon, BMPEA, and *Acacia rigidula* in virtually every cause of action. Specifically, the state unfair trade practices claims here rely on the proposition that picamilon BMPEA, and *Acacia rigidula* are not lawful dietary ingredients or dietary supplements and that the Products’ Nutrition Labels does not adhere to the FDCA requirements because these ingredients are not lawful dietary ingredients. As in the FAC, Plaintiffs rely on the federal definitions to establish the “unlawful” element of their state claims and even support that proposition by pointing to 21 U.S.C. § 321(ff), 21 U.S.C. § 331(a), 21 U.S.C. § 350(b) and other relevant provisions of the FDCA. (See SAC ¶¶ 30, 34.) In their SAC, Plaintiffs now make allegations for the first time that the Products violate the FDA’s nutrition labeling requirements for listing dietary ingredients, citing specifically to 21 U.S.C. § 343. (SAC ¶¶ 36-38.) However, this new allegation stems from the same allegations contained in the FAC—that labeling requirements are violated because these ingredients are listed as dietary ingredients when they should not be because they are allegedly unlawful under the FDCA. All these additional allegations do is make it even more clear the extent that Plaintiffs are relying on the FDCA and attempting to bring an enforcement action of its provisions, an action that is in the sole purview of the FDA.

The nature of Plaintiffs’ allegations demonstrate that Plaintiffs’ claims fail the basic *Riley* test for preemption because the claims would not give rise to recovery in the absence of the FDCA. Plaintiffs’ allegations depend entirely upon a conclusion that has not yet been reached:

namely that picamilon, BMPEA, and *Acacia rigidula* have been deemed unlawful pursuant to the FDCA (a determination that may be made only by the FDA under its rule-making powers or through an enforcement action in district court). *See* 21 U.S.C. §§ 332-334. Because the ingredients have not been deemed unlawful by FDA there can be no state law claims because no standard has been violated. The question of whether a "dietary supplement" is "lawful" exists solely because of the federal FDCA, and in the absence of the FDCA, no allegedly wrongful conduct remains. Because picamilon, BMPEA, and *acacia rigidula* were not declared unlawful dietary ingredients by the FDCA at the time Plaintiffs allege to have bought the products and have never to date been declared as such, the entirety of Plaintiffs' case collapses.

D. There Has Been No FDA Enforcement or Final Agency Action as to Picamilon, BMPEA or Acacia Rigidula.

For Plaintiffs' claims to survive this motion, they must demonstrate the impossible, namely that there has been final agency action against GNC as to both picamilon, BMPEA, and *acacia rigidula*. Plaintiffs cannot even show the initiation of an enforcement action against GNC, or anyone else, let alone a final agency action.

As a general matter, two conditions must be satisfied for an agency action to be "final." First, the action must mark the consummation of the agency's decision making process—it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (internal citations and quotation marks omitted); see *AT & T Co. v. EEOC*, 270 F.3d 973, 975 (D.C.Cir.2001). As is set forth below, declarations and warning letters do not constitute enforcement actions and cannot be deemed final agency actions.

i. The Welch Declaration Does Not Constitute an Enforcement Action or Final Agency Action.

Nowhere in the FDCA is there any provision stating that an enforcement action can be initiated by way of a declaration of an FDA official. To find that such any declaration constitutes a FDA enforcement action would be unprecedented. *See Biotics Research Corporation v. Heckler*, 710 F.2d 1375 (1983) (holding that regulatory letters issued by the FDA did not constitute a final decision by the FDA and that letters did not commit the FDA to enforcement action.) To be clear, the Welch Declaration is nothing more than Dr. Welch's view.⁷

Moreover, such a declaration fails to meet the requirements of final action under the Administrative Procedures Act (“APA”), as it does not appear to mark the culmination of any decision-making process and rights or obligations are not determined. *See* 5 U.S.C. § 704. Additionally, it cannot be said to be something from which legal consequences will flow because it was never even provided to GNC by the FDA. Put simply, the Welch's Declaration cannot be deemed an enforcement action or final agency action—a fact that Plaintiffs acknowledge by failing to allege that the Welch Declaration rises to such a level. In reality, the only actual use of the Welch Declaration has been as an exhibit in support of the OAG action!

ii. Warning Letters Are Not Enforcement Actions or Final Agency Actions.

Most courts to consider the question have held that an FDA warning letter does not constitute a final agency action. *Cody Labs., Inc. v. Sebelius*, 446 Fed. App'x 964, 969 (10th Cir. 2011). Instead, FDA warning letters are considered informal and advisory. *See*, FDA

⁷ 21 CFR 10.85(k): “A statement made or advice provided by an FDA employee constitutes an advisory opinion only if it is issued in writing under this section. A statement or advice given by an FDA employee orally, or given in writing but not under this section or 10.90, is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.”

Regulatory Practices Manual—March 2017; 4-1-1.⁸ Indeed, warning letters are not even the initiation of an enforcement action. *Holistic Candlers and Consumer Ass'n v. U.S. Food and Drug Admin.*, 770 F.Supp.2d 156, 160-161(D.D.C. 2011), *aff'd sub nom. Holistic Candlers and Consumers Ass'n v. Food & Drug Admin.*, 664 F.3d 940(D.C. Cir. 2012). Although GNC took swift action to remove all products at issue referenced in the FDA's warning letters, the fact remains that the FDA has never pronounced either ingredient to be unlawful. Moreover, the warning letters were never directed to GNC and some of the letters GNC never received. (Chery Dec. ¶ 11.)

Indeed, warning letters simply communicate the agency's position on a matter without committing the FDA to an enforcement action. *See*, FDA Regulatory Practices Manual—March 2017; 4-1-1. (See Request for Judicial Notice and Declaration of Amy B. Alderfer, Ex. L.) A Warning Letter typically results in a process of discussion, negotiation, and analysis involving the FDA and interested parties. Following this process, the FDA may choose to modify or rescind a Warning Letter altogether.

For that reason, even the FDA itself does not consider a warning letter a final action on which it can be sued. *Holistic Candlers and Consumers Ass'n v. Food & Drug Admin.*, 664 F.3d at 944-45. After issuing a Warning Letter, the FDA may choose to initiate enforcement proceedings, which may result in a final agency action and resulting appeal. Unless and until that occurs, however, there has been no binding resolution of the issues raised in the Warning Letter.

To this date, questions regarding the legality of BMPEA, picamilon, and *Acacia rigidula* are far from settled. The Warning Letters are simply preliminary statements of the agency's

⁸ <http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074330.pdf> (Alderfer Dec., Ex. L.)

position, which may be modified or rescinded by the agency or rejected in a subsequent enforcement action or appeal. Accordingly, although the FDA may have issued Warning Letters for some products containing BMPEA, picamilon, and *Acacia rigidula*, it does not follow that the issue of the lawfulness of these ingredients is now undisputed. These letters are one step in a process, but not a final determination. What's more, even ignoring the above legal truisms, GNC had begun removing (1) BMPEA products 12 days before the FDA BMPEA warning letters were sent to others, (2) over 60 days before the FDA picamilon warning letters were sent to others; (3) almost a year before the FDA *Acacia rigidula* warning letters were sent to others.

iii. Allowing Declarations and Warning Letters to Serve as Final Agency Action for Purposes of this Litigation Would Deprive GNC of Its Due Process Rights.

Under the APA there is a judicial right of review of “final agency action for which there is no other adequate remedy in a court.” 5 U.S.C. § 704; *see Trudeau v. Federal Trade Com'n*, 456 F.3d 178, 185 (D.C. Cir. 2006) (“If there was no final agency action ..., there is no doubt that appellant would lack a cause of action under the APA.”” (quoting *Reliable Automatic Sprinkler Co. v. Consumer Prod. Safety Comm'n*, 324 F.3d 726, 731 (D.C.Cir.2003))). As noted in *Holistic Candlers and Consumers Ass'n v. Food & Drug Admin.* 664 F.3d at 943, the “FDA's warning letters fail to satisfy either condition: they neither mark the consummation of the agency's decision making process nor determine the appellants' legal rights or obligations.”

Here, Plaintiffs are seeking to hold up as “final” action form warning letters and a declaration, things which do not even initiate an action let alone indicate final agency action. Moreover, GNC had no legal opportunity to challenge the warning letters and the declaration as they would not have been considered “final action” subject to judicial review. To be sure, had GNC attempted to challenge either the declaration or the warning letters it would have been found to have no cause of action under the APA as FDA would have argued that these were not

final actions. Thus, allowing a declaration and warning letters to serve as final actions for purpose of this litigation would rob GNC of its due process rights, as GNC would be bound by a declaration and warning letters that it had no ability to challenge in a judicial action because they did not constitute final action under the APA. Moreover, how is GNC supposed to have notice of the actions of certain FDA officials, which do not amount to agency action or FDA enforcement actions, remains a mystery. Forcing GNC to respond to sub rosa FDA “action” is tantamount to being put on “double secret probation.” Finally, it is axiomatic that if BMPEA, picamilon, and *Acacia rigidula* were not unlawful under the FDCA, the mislabeling and adulteration claims here would not lie.

E. Plaintiffs’ Claims Should Be Dismissed Because of the FDA Guarantee.

The FDCA provides penalties for persons who violate certain provisions of the Act. However, Section 303, paragraph (c) of the Act states that no person shall be subject to the penalties of subsection (a)(1) for having received, or proffered delivery of, adulterated or misbranded food additives if he has established a good faith guarantee from whom he received the articles. This paragraph was included in the 1958 amendments to the Federal Food, Drug and Cosmetic Act and remains the legal basis for the "letter of guaranty" supplied by many manufacturers to their clients.⁹

Here, GNC did not manufacture or sell under the GNC brand any products containing BMPEA, picamilon, and *Acacia rigidula*. (Cherry Dec. ¶ 2; SAC ¶ 88.) Moreover, GNC can establish that its third-party vendor agreements provide that the vendors warranted that the goods were manufactured, packaged, stored and shipped in accordance with the applicable standards of Good Manufacturing Practices promulgated under the FDCA and all applicable federal, state,

⁹ See <http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/Notifications/ucm095327.htm> (Alderfer Dec., Ex. M.)

and local laws, rules and regulations. GNC is entitled to rely on its vendors pursuant to the plain terms of the FDCA. The FDA Guarantee provides GNC with immunity from misdemeanor prosecution under the FDC Act, limiting even FDA's ability to prosecute violations where intent is absent, and establishing that Congress did not intend that retailers who rely in good faith on the guarantees of third party vendors be held accountable for the actions of those vendors, except in unusual circumstances not present here. Accordingly, plaintiffs cannot state a claim for relief.

F. Plaintiffs' Claims Fail Because the FDCA Requirements Plaintiffs Cite Regarding Premarket Notification Apply to Manufacturers and Distributors and Not Retailers like GNC.

Plaintiffs' SAC focuses on allegations that GNC is somehow liable to Plaintiffs because it failed to follow the FDA new dietary ingredient notifications. (SAC ¶¶ 29-39.) But these allegations are completely inapplicable as to GNC because the new dietary ingredient notifications are requirements for manufacturers and distributors, not retailers like GNC.

A "new dietary ingredient" ("NDI") is "a dietary ingredient that was not marketed in the United States in a dietary supplement before October 15, 1994" 21 U.S.C. § 350b(d). The FDA states: "There is no authoritative list of dietary ingredients that were marketed in dietary supplements before October 5, 1994. Therefore, manufacturers and distributors . . . are responsible for determining if an ingredient is a 'new dietary ingredient'" See "*New Dietary Ingredients in Dietary Supplements - Background for Industry,*"¹⁰ (Alderfer Dec., Ex. N.) (Emphasis Added.) If the manufacturer or distributor believes that an ingredient is an NDI, and is not exempt from the NDI pre-market notification requirement, the manufacturer or distributor must submit "information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such

¹⁰ <https://www.fda.gov/Food/DietarySupplements/NewDietaryIngredientsNotificationProcess/ucm109764.htm>

dietary ingredient will reasonably be expected to be safe.” See 21 U.S.C. § 350b(a)(2). None of the NDI pre-market notification requirements pertain to retailers.

Plaintiffs admit that GNC is a “retailer of nutritional supplements.” (SAC ¶ 41.)

Plaintiffs do not allege that GNC manufactured any of the Products that are subject to this action, and in fact, specifically name the manufacturers of the subject Products. (SAC ¶ 88.) Moreover, a distributor is clearly different than a retailer. A distributor is defined as “[a] wholesaler, an individual, corporation, or partnership buying goods in bulk quantities from a manufacturer at a price close to the cost of manufacturing them and reselling them at a higher price to other dealers, or to various retailers, but not directly to the general public.”¹¹ Here, Plaintiffs make no allegations that GNC sold the subject Products to anyone other than the Plaintiffs and general public. Thus, GNC is not considered a distributor of the Products.

Because GNC is not a manufacturer or distributor of the Products, GNC had no legal duty to submit any NDI premarket notification to the FDA. This is further supported by the fact that none of the warning letters referenced in the SAC were addressed to GNC. (Alderfer Decl., Ex. C, G, & H). Thus, any allegations regarding violations of NDI premarket notifications fail.

V. CONCLUSION

For the reasons set forth above, GNC respectfully requests that this Court grant its Motion to Dismiss Plaintiffs’ SAC in its entirety.

Dated: October 20, 2017

/s/ Amy B. Alderfer

Amy B. Alderfer
Cal. I.D. No. 205482 (*Admitted Pro Hac Vice*)
Brett Taylor
Cal. I.D. No. 274400 (*Admitted Pro Hac Vice*)
Cozen O’Connor
601 S. Figueroa Street, Suite 3700
Los Angeles, CA 90017

¹¹ <https://legal-dictionary.thefreedictionary.com/Distributor>

Paul K. Leary , Jr.
I.D. No. 85402 (*Admitted Pro Hac Vice*)
Cozen O'Connor
1650 Market Street Suite 2800
Philadelphia , PA 19103
(215) 665-6911
Email: Pleary@cozen.com

Mark E. Utke
I.D. No. 70750
Cozen O'Connor
1650 Market Street Suite 2800
Philadelphia, PA 19103
(215) 665-2164
Email: Mutke@cozen.com

*Attorneys for Defendant
General Nutrition Corporation*